(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
11 January 2001 (11.01.2001)

PCT

(10) International Publication Number
WO 01/02979 A2

(51) International Patent Classification[7]: G06F 17/00

(21) International Application Number: PCT/IB00/00880

(22) International Filing Date: 30 June 2000 (30.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
99/4267 30 June 1999 (30.06.1999) ZA
2000/0694 14 February 2000 (14.02.2000) ZA

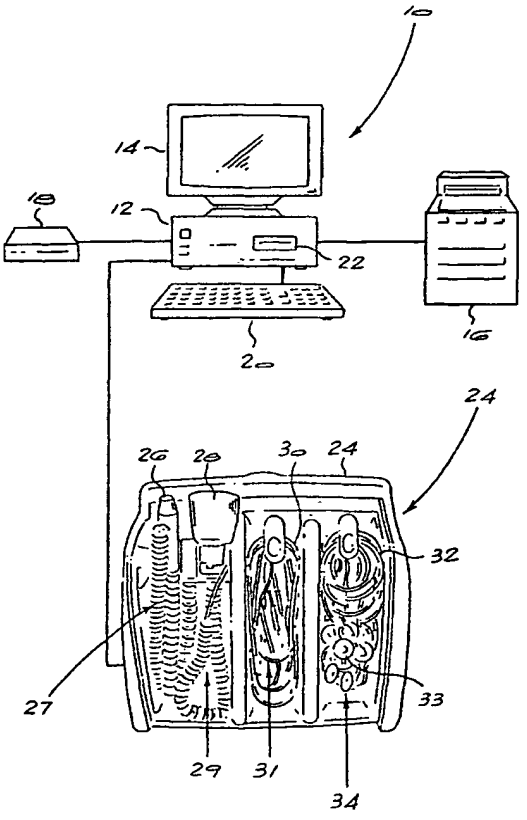
(71) Applicant *(for all designated States except US)*: SUNESI CLINICAL SYSTEMS (PROPRIETARY) LIMITED [ZA/ZA]; 1st Floor, 240-250 Main Road, Retreat, 7945 Cape Town (ZA).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: MANOJLOVIC, Mirko [YU/ZA]; 856 Main Road, 7975 Scarborough (ZA). HALLAUER, Mike [ZA/ZA]; 15 Suddie Close, 7945 Tokai (ZA). SEARLE, Harold, Richard [ZA/ZA]; 15 Suddie Close, 7945 Tokai (ZA). HOLMAN, Allan, Frank [ZA/ZA]; 1 Stuart Place, Cresta Ext. 1, 2194 Randburg (ZA). BHAMJEE, Ahmed, Sayed [ZA/IE]; 1 Orchard Square, The Maples, Clonskeagh, 14 Dublin (IE). GOEMANS, Brian, Clement [ZA/ZA]; 7 Parade Crescent, 7800 Constantia Hills (ZA). GIESLER, Achmed [DE/ZA]; 17 Onrus Street, De Bron, 7530 Bellville (ZA). BOONZAAIER, David, Anthony [ZA/ZA]; 23 Roseberry Road, 7700 Mowbray (ZA). SOLMS,

[Continued on next page]

(54) Title: ACQUIRING MEDICAL DATA FROM A PATIENT AND PROCESSING THE DATA



[Continued on next page]

WO 01/02979 A2

Justin [ZA/ZA]; 16 Portswood Mews, Thornhill Drive, 8005 Green Point (ZA). **WRIGHT, Raymond, Edward** [ZA/ZA]; 8 Muscat Way South, 7806 Constantia (ZA). **WRIGHT, Ray** [ZA/ZA]; 8 Muscat Way South, 7806 Constantia (ZA).

(74) **Agents: DOWER, John, Christopher** et al.; Spoor and Fisher, P.O. Box 41312, 2024 Craighall (ZA).

(81) **Designated States** *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) **Designated States** *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— *Without international search report and to be republished upon receipt of that report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(57) **Abstract:** A diagnostic apparatus (10) for acquiring medical data from a patient and for processing such data includes a PC (12) and its standard peripherals, namely a monitor (14), a printer (16), an internet modem (18) and a keyboard (20). The PC (12) is linked to a diagnostic unit (24) incorporating diagnostic test hardware. The unit (24) is provided with a series of diagnostic modules, including a pneumotach (26) for measuring airflow and representing the front end of a spirometer module (27), a non-invasive blood pressure module (29), a body composition measurement module (31), and an ECG module (34). Raw data is transferred from the diagnostic unit (24) to the PC for further processing and display. The processed data is assessed and the raw data from which the processed data has been derived is then stored in a database associated with the PC for retrieval and processing at a later stage.

ACQUIRING MEDICAL DATA FROM A PATIENT AND PROCESSING THE DATA

FIELD OF THE INVENTION

THIS invention relates to acquiring medical data from a patient and to the processing of such data.

BACKGROUND OF THE INVENTION

In doctors' rooms a range of diagnostic equipment is found. Such equipment can be of relatively unsophisticated form and comprise, for example, a stethoscope, a thermometer, a weighing machine, a blood pressure manometer, an exercise device for raising pulse rate, etc, In the rooms of a specialist the equipment to be found will depend on the nature of the specialisation. A cardiac specialist will have an array of equipment Including an electrocardiograph. A specialist physician will have devices for checking lung function and a urologist devices for checking the characteristics of urine flow. A neurologist will have an encephalograph, and other practices will have X-ray apparatus and ultrasound imaging equipment.

In less sophisticated practices a patient's record will generally be written on a card forming part of a paper record or other such filing system. In other practices the written patient's record may be captured on a personal computer by the doctor himself or by a secretary from notes the doctor makes.

Current state health policy in many developing countries, including South Africa, is to divert resources to what is called primary healthcare. This means

that the medical professional who first sees the patient, and who could be a nurse or doctor, needs to be able to do more extensive and accurate tests than hitherto. With the medical equipment presently available this would necessitate the purchase of many different types of equipment, and budgetary constraints make this impossible.

OBJECTS OF THE INVENTION

It is the general object of the present invention to conduct diagnostic tests, to capture the data from these tests in a form that can be readily stored, displayed, analysed, replayed and trended, as well as shared over the Internet.

It is the further object of the present invention to store data from disparate diagnostic test procedures in one unified patient health database. This unified database, which can be extended by the addition of other diagnostic test procedures, facilitates the trending and archiving of patient health data for future reference, referral and consultation.

SUMMARY OF THE INVENTION

According to a first aspect of the invention there is provided a medical diagnostic apparatus comprising testing means for performing diagnostic tests on a patient, pre-processing means for deriving raw test data from the testing means, processing means for processing the raw test data into a user-discernible format, compression means for compressing the raw test data, and storage means for storing the compressed raw test data for subsequent processing.

In a preferred form of the invention, the medical diagnostic apparatus includes display means for displaying the processed data in the user-discernible format, and selection means for selecting a raw data storage option on the basis of the displayed processed data.

Conveniently, the testing means includes means for performing at least two tests chosen from a group comprising tests based on bio-electrical activity, tests based on blood pressure, tests based on lung function, and tests based on body composition.

Typically, the means for performing tests based on bio-electrical activity include an ECG testing module, the testing means for performing tests based on blood pressure includes a non-invasive blood pressure testing module, the testing means for performing tests based on lung function includes a spirometer module, and the testing means for performing tests based on body composition includes a body composition testing module.

Advantageously, the modules form part of a diagnostic unit which is arranged to transfer the raw data to a computer means for subsequent processing and storage.

By the tem "raw data" is meant data in respect of which the signal component has not been extracted from a composite of noise and signal within the band of interest.

Typically, the pre-processing means may include a primary filtering means for removing out-of-band noise in respect of bandwidths which do not have a signal component of interest.

Conveniently, the in-band filtering means is software-based, and is arranged to run on the computer means.

Buffer means are preferably provided for temporarily storing the raw data prior to selecting the raw data storage option for compressing and storing the raw test data for subsequent retrieval and processing thereof.

Conveniently, the database is linked to or forms part of a clinical patient record database, and is arranged to receive raw test data in respect of all of the tests and to include historical raw test data in respect of a plurality of patients.

Typically, historical raw test data is arranged to be processed with current raw test data using the same processing algorithms to achieve consistency for the purposes of trend analysis in respect of individual patients or for the purposes of comparing patients within a population group.

The invention extends to a method of acquiring medical data on a patient including the steps of deriving raw test data in electronic format from diagnostic tests which have been performed on the patient, processing the raw test data into a user-discernible format, compressing the raw test data, and storing the compressed raw data for subsequent retrieval and processing.

In a preferred form of the invention, the method includes the step of displaying the processed data in the user-discernible format, and selecting a raw data storage option on the basis of the displayed processed data.

Conveniently, the raw test data is processed in accordance with one or more software-based algorithms to extract in-band noise from a composite of noise and signal within the band(s) of interest.

Advantageously, the method includes the step of pre-processing the raw test data by removing out-of-band noise in respect of bandwidths which do not have a signal component of interest.

The method typically includes the steps of obtaining raw analogue data from pressure variation tests, converting the analogue data to digital form, compressing the raw digital data and storing the compressed digital data in a common database for subsequent retrieval and processing thereof.

The pressure variation tests may include non-invasive blood pressure tests and lung function or spirometry tests.

The method may further include the steps of obtaining raw analogue data from bio-electrical tests, converting the analogue data to digital form, compressing the raw digital data and storing the compressed digital data in a common database for subsequent retrieval and processing thereof.

Advantageously, the method further includes the steps of obtaining raw analogue data from body composition tests, converting the analogue data to digital form, compressing the raw digital data and storing the compressed digital data in a common database for subsequent retrieval and processing thereof.

Conveniently, the method includes the subsequent steps of retrieving and decompressing the stored raw test data, processing data into a user-discernible format, in accordance with a software-based processing algorithm which is different to the software-based algorithm used originally to process the raw test data at the time of capture.

Typically, the method includes the further steps of storing in the common database clinical patient records, compiling a history of raw test data in respect of each patient, retrieving the raw test data and processing it in accordance with at least one common algorithm for subsequent trend interpretation.

BRIEF DESCRIPTION OF THE DRAWINGS

For a better understanding of the present invention, and to show how the same may be carried into effect, reference will now be made, by way of example, to the accompanying drawings in which:-

Figure 1 is a highly schematic diagrammatical representation of diagnostic apparatus in accordance with the present invention;

Figure 2 is a flow chart broadly illustrating the overall data capture procedure;

Figure 3 is a flow chart broadly illustrating the diagnostic procedure;

Figure 4 shows a program structure diagram of top level module hierarchy;

Figure 5 shows a program structure diagram of ECG module hierarchy;

Figure 6 shows a program structure diagram of non-invasive blood pressure module hierarchy;

Figure 7 shows a program structure diagram of spirometer module hierarchy;

Figure 8 shows a program structure diagram of body composition module hierarchy;

Figure 9 illustrates the database structure of the diagnostic apparatus of the invention;

Figure 10 is a schematic block diagram of the high level system modules;

Figure 11 is a schematic block diagram of the diagnostic apparatus of the invention;

Figure 12 is a functional block diagram of a diagnostic apparatus of the present invention;

Figure 13 shows a more detailed functional block diagram of the front end of an ECG signal processing path;

Figure 14 shows a functional block diagram of a common processing path to which the ECG signal path of Figure 13 is connected;

Figure 15 shows a functional block diagram illustrating the PC signal processing path of the ECG signals downstream of the common processing path;

Figure 16 shows a functional block diagram of off-line PC processing of captured raw ECG data;

Figure 17 shows a functional block diagram of a spirometry signal processing path;

Figure 18 shows a functional block diagram of a non-invasive blood pressure signal processing path; and

Figure 19 shows a functional block diagram of a body composition signal processing path.

DESCRIPTION OF EMBODIMENTS

Referring first to Figure 1, diagnostic apparatus 10 includes a computer 12 in the form of a PC. The peripherals provided in conjunction with the computer are a monitor 14, a printer 16, an internet modem 18 and a keyboard 20. The computer has standard drives 22 for receiving storage mediums such as floppy discs, stiffies and CD ROM's.

The PC 12 is linked to a diagnostic unit 24 incorporating diagnostic test hardware. The diagnostic unit 24 is provided with a series of diagnostic modules, including a pneumotach 26 for measuring airflow and representing the front end of a spirometer module 27, an inflatable cuff 28 for non-invasive blood pressure (NIBP) measurement and forming part of a NIBP module 29, a series of four leads 30 forming part of a body composition measurement module 31, and ten ECG leads 32 carrying ECG electrodes 33 forming the front end of an ECG module 34.

Figure 2 illustrates the way in which the system is used to secure medical data pertaining to a patient. The software used is herein referred to as the "diagnosa" software. Once the software is running, a password is entered to gain access either to the record of an existing patient or to create a new patient record. A record is then created for the new visit. At this stage the diagnostic procedure to be undertaken is selected and the appropriate diagnostic module is connected to the patient. It will be understood that the number of diagnostic modules may be increased, or other diagnostic modules substituted, depending on the nature of the health practitioner's work.

The flowchart of Figure 3 shows the diagnostic procedure followed in PC-based processing of the signal received from one of the diagnostic modules. Configuring the diagnostic module may involve setting certain parameters specific to the diagnostic test to be carried out. The raw data received is processed in real time and is displayed. Thereafter, a decision is made as to whether the data needs to be stored or not. If so, the data is stored in the patient record forming part of the database. It will be noted from the flowchart that it is the received raw or unprocessed data which is temporarily stored or buffered and is then compressed before being stored in the patient record within the database.

Since the data is stored in raw unprocessed form any new or improved processing algorithm can be applied to the data at a future time. Thus the longevity of the date is ensured. If the data is stored in processed form, and the technique used to analyse or interpret the data is changed, then the previously stored data becomes unusable. It will be understood that the term unprocessed indicates that the information derived from the test remains in the form in which it was obtained. The incoming signal will, of course, usually have been subjected to a conditioning process to exclude extraneous noise, that forms no part of the raw data which it is desired to store.

It will be appreciated that, whilst certain hardware pre-processing of the data takes place, the processing algorithms used to arrive at the final graphical displays are software-based. In addition, all of the signal pre-processing that takes place in the diagnostic unit includes the removal of out-of-band noise falling outside the bandwidths of interest. As a result, the raw signal content is preserved, with all in-band noise only being removed during the software signal processing routine. Improved processing and noise extraction algorithms can thus be applied to this raw stored data at any later stage, as the signal content has not been degraded in any way.

Figure 4 is a program structure diagram showing the hierarchical levels of the programmes and sub-programmes for implementation in code, in this case C++. In Figures 5 to 8, the program structure diagrams in respect of the individual modules are shown, from which it is similarly clear that the unprocessed or raw data is only stored in the database after compression.

The structure of the database is shown in more detail in Figure 9, on a per system, per user, per patient and per patient per test basis.

Referring now to Figure 10, the diagnostic system includes three major subsystems: data acquisition, diagnostics and clinical patient records (CPR). These together comprise an integrated digital diagnostic system delivering diagnostic information for interpretation by the physician as well as storage thereof in the database and dispersal via electronic mail or explicit interfaces to third party systems.

The data acquisition subsystem or unit consists of the diagnostic test hardware (DTH) which is controlled by an embedded microprocessor, and the software which communicates with the DTH on the PC. The microprocessor merely serves as an interface between the diagnostic software and the diagnostic test hardware. The microprocessor implementation follows the nested cyclic executive paradigm. It is platform-dependent and is implemented in C and assembler.

The diagnostic subsystem or unit enables the physician to acquire information via the DTH about the state of the patient currently under consideration. It provides tools for performing and interpreting a diagnostic test and providing the other services that are required by the physician within this context. This subsystem is divided into the following diagnostic test modules:-

- *ECG* - The capture, display, analysis and hardcopy of an electrocardiogram (refer to Figure 5).
- *Spirometry* - The capture, display, analysis, interpretation, trending and hardcopy of patient lung function (refer to Figure 7).
- *NIBP* (Non-invasive Blood Pressure) - The capture, display, analysis, interpretation and trending of oscillometric blood pressure waveforms and parameters (i.e. systolic, diastolic, mean arterial blood pressure and heart rate) (refer to Figure 6).
- *Body Composition* - The derivation of patient body content ratios from bloimpedance measurement, and subsequent analysis, trending and hardcopying (refer to Figure 8).

These are the four most important tests and enable an overall analysis of the patient's condition to be made. Other tests can be added or substituted for the four mentioned.

The diagnostic subsystem is further subdivided into layers according to the nature of the computing platform, the interface between it and the DTH and the DTH itself. These layers can be largely grouped into those responsible for the presentation of the user interface (view) and those responsible for the remainder of the functionality (model). The presentation layers are not platform independent and are implemented using Borland C++ Builder. The model layers are platform independent and are implemented using ISO C++. A bridge layer is used to provide access to the platform services that are directly required by the model layers. The module layers are usefully further structured into a pipes and filters architecture which is a convenient model for the flow of diagnostic data sample processing.

The clinical patient records (CPR) provides the supporting infrastructure for long term storage of diagnostic tests and patient data, identification of patients and physicians and other administrative functionality required to manage the

data acquired and manipulated via the diagnostic subsystem. The records are platform dependent and are implemented in Borland C++ builder.

The two subsystems are linked by a narrow interface which is designed to allow the implementation of a wide variety of CPR systems without affecting the diagnostic core subsystem. The diagnostic subsystem can be seen as a component which is plugged into some CPR system to provide specialised functionality. This is an example of a layered architecture where the diagnostic subsystem is layered on the CPR.

The architecture uses a component-based approach. Any particular instance of the system is constructed from a number of independent components. A different version of the system can be constructed by assembling the standard components in a different manner. The components are themselves assembled from lower level components.

The usage of components is particularly important in the context of a medical device which requires an FDA (or similar) certification process. A new system should only require the certification of the new components and not those that have previously been certified. This requires a version control mechanism which precisely identifies each component so that it can be tied to a previous certification.

Much of the near term extension to the current system will affect the CPR subsystem which does not itself require the same level of certification as a medical device. The component architecture allows the two subsystems to be tightly integrated at the application level, providing a high quality user interface, while allowing separation at the certification level.

The component architecture facilitates an incremental development plan and simplifies the construction of test harnesses.

Provision is made for interfaces to future billing (i.e. accounting) and logistics subsystems. The logistics subsystem will provide logging of failures, calibrations and other data that is required to support quality control and maintenance activities. Provision is also made for the email of diagnostic test files and subsequent viewing thereof on remote systems.

To provide a general overview of the invention reference will now be made to Figures 11 and 12. In Figure 11 the bottom line indicates the types of modules that can be used to acquire patient information. Initial hardware-based signal conditioning usually involves amplification and can also involve a degree of filtering to remove extraneous signals. The serial link connects the diagnostic equipment of the diagnostic unit 24 to the computer 12 used by the medical practitioner.

In figure 12 the diagnostic unit 24 includes a central microprocessor 35.1 linked to the modules 27, 29, 31 and 34 via a multiplexer 56 and an analogue to digital converter 62. The microprocessor 35.1 also controls the operation of an NIBP pump 136 and an additional pump 35.2 for an other instrument to be added in the future. The RS232 link 66 links the microprocessor 35.1 to the PC 12. Additional outputs from the microprocessor include fluids and metrics systems 35.3 and 35.4 which may similarly be added in the future, an annunciator 35.5 to indicate a hardware failure, together with a series of display LED's 35.6.

The software system of the computer converts the signals generated by the transducers into the patient record. As the signals received are indicative of the tests carried out, the software can also include programs for converting the received information into billing records.

The diagnostic apparatus of the invention will now be described in greater detail with reference to the various modules described above. In Figure 13, a front end of the ECG module 34 is shown in which a patient indicated schematically at 40 is linked to the ten ECG leads 32. Nine of the leads represent input channels, and include three limb leads 32.1, six pre-cordial or chest leads 32.2 and an anti-noise output lead 32.3 which drives an anti-noise feedback signal derived from the three limb signals back onto the patient to suppress the ambient noise. All of the nine input lead channels 32.1 and 32.2 follow the identical signal processing path through a 120Hz low pass filter 42, an amplifier 44, a 0.03Hz high pass filter 46 and a sample-and-hold circuit 48. The nine conditioned input signals are fed to a multiplexer 50 where they are reduced to a single time-switched output signal which undergoes further amplification at an amplifier 52 before being presented to a common processing path 54. The common processing path 54 is illustrated in more detail in Figure 14, and includes a second main multiplexer 56 which has four inputs 58.1 to 58.4 leading from the various diagnostic modules. The multiplexer is used to link one of the inputs 58.1 to 58.4 to the single output 60, depending on which test is selected via the PC 12. The output signal is digitised by an analogue to digital converter 62, and the digital data is assembled into a packet 64 which is then transmitted to the PC 12 over the RS232 opto-isolated serial link 66.

At the PC, a low level interrupt driven process 68 picks up the bytes as they are received by the serial port, and stores them in a buffer 70. A higher level error detection process 72 extracts full packets, checks them for integrity and passes on the data to the next higher level, which represents the end of the common processing path 54 to which all the incoming signals from the input leads 58.1 to 58.4 are subjected.

Referring now to Figure 15, the ECG signals undergo a signal reconstruction routine 74 in which the serial outputs are reconstructed into nine separate

output channels 76 from which the ECG waveforms having a signal content from 0.03Hz to 120Hz are ultimately re-created from the raw data. In a real time PC-based signal processing path 78, the ECG waveform signals undergo scaling at a calibration reference 80 which converts the data to mV. The scaled signals are then filtered through a digital notch filter 82 to remove power noise from the 50Hz mains. A base line wander filter 84 is then used to remove low frequency components. A muscle noise filter 86 removes muscle noise, and a subsequent low pass filter 88 removes high frequency components above the frequencies of interest. A summation process 90 is used to derive six output waveform signals 92 from the three input limb signals 94. These are plotted in real time together with the six pre-cordial signals 96 which have been through identical real time signal processing paths identical to the path 78 to arrive at a real time graphical display 98.

At the same time that the raw data undergoes real time processing, it is temporarily stored in a buffer 100. When the user chooses to save a test result, this raw data is then transferred from the buffer 100 into a common database 102 in compressed form using a Lif-Zimpel-Walsh compression technique.

After the data has been captured, and when it is retrieved from the database 102 at a later stage, a more time-intensive signal processing strategy is applied to remove more noise than is possible in real time. Referring now to Figure 16, the raw compressed data from the database 102 or (104) from the buffer 100 is retrieved and decompressed, and is then passed through a low pass filter 106 after which it is analysed in the frequency domain using Fourier analysis, as is shown at 108. A dynamic threshold is applied in the frequency domain to identify in-band noise peaks and their harmonics, which are then removed at 110. This signals processing approach deals both with base line wander and power noise. The processed waveforms are displayed at the display 98, and may also be printed.

Referring now to Figure 17, the spirometer module 27 includes the pneumotachometer 26 in the form of an orifice plate flow transducer which produces an air pressure converted to an electrical signal by a pressure transducer 114. The output of the pressure transducer is amplified by means of an amplifier 116 is filtered by a 72Hz low pass filter (not shown), and is then presented to the common signal processing path 54 which has already been described in detail with reference to Figure 14. The signal emerges from the common processing path in the PC at a spirometry processing input forming part of a dedicated spirometer signal processing path 118, having frequency components of interest in the range 1Hz to 20Hz. The flow versus time signal from the common processing path is converted by scaling software 120 to litres per second using calibration data stored in the common database 102. The spirometer is calibrated on a regular basis to derive a relationship between digital units and flow rate. The calibration is based on a number of strokes of a three litre air syringe. The user is required to execute strokes of differing flow velocity in respect of the known volume, whereafter a numerical computation over the varying flow strokes yields a calibration curve which is then stored in the database 102.

The flow rate versus time signal is then numerically integrated at 122 to yield volume, and the relationship of flow versus volume is derived. A Savitsky-Golay filter 124 is applied to the signal to suppress power noise whilst retaining peak excursions. Start of the positive flow is back-extrapolated at 126 to identify the graph zero point, and thresholds are applied to identify the zero flow points. Thereafter, the flow versus time and flow versus volume waveforms are used to calculate the parameters of interest at 128, and the flow versus volume graph is displayed at 130 and printed if required.

As was the case with the ECG data, when the user chooses to save the test results, the raw flow versus time test data which was temporarily stored in the

buffer 132 is compressed to reduce storage space and is stored in the database 102. The raw spirometry data from the database 102 can be read back from the database at any time, and, unlike the ECG data, the raw stored data goes through the same processing path as the live data, ultimately to derive the flow versus volume graph and other parameters of interest.

Referring now to Figure 18, the non-invasive blood pressure module 29 include the inflatable cuff 28 which is wrapped around the arm of the patient. The cuff is inflated by the pump 136 and deflated by valves 138 in the diagnostic unit 24 under control of software in the PC 12. The pressure in the cuff 28 is measured by a pressure transducer 139 which converts the pressure into an electrical signal presented directly to the common processing path 54, as is shown at 58.3A. A filtered signal is similarly presented to the common processing path 54 via a filtered input 58.3B after it has passed through a high pass 4Hz filter 140 to remove the DC component and a low pass 20Hz filter 142 to remove power noise. These two signals then pass through the common processing path 54 to emerge at the input of the PC-based NIBP signal processing path 145. The signals are converted to mmHg in a scaling routine 146 using calibration data stored in the diagnostic unit 24 during manufacture thereof.

The two pressure versus time signals are filtered using a Savitsky-Golay filter 148 to remove remaining inband (4-20Hz) noise and are displayed on a display 150 as pressure versus time curves. The primary unfiltered signal shows the cuff pressure, and the filtered signal shows the oscillations caused by the arterial blood pressure pulses which are superimposed on the primary unfiltered signal.

The cuff 28 is first inflated to a defined maximum pressure, and is then allowed to deflate at a controlled rate. As the pressure drops, the oscillations first increase then decrease in amplitude. Curves are fitted at 152 to the peak

oscillation points, with the inflection points of these curves identifying the pressures of interest, namely systolic, diastolic and mean arterial pressures. The pulse rate measures the average period of the pulses. Three measurements are usually taken, with the result given as the average of the three.

In the event of the user choosing to save a test result, the raw data waveforms from the common processing path 56 temporarily stored in the buffer 154 are then stored in a compressed form in the common database 102. The stored raw data can be retrieved and processed at any stage via the PC-based NIBP signal processing path 145. It will also be appreciated that, in the event of other algorithms being developed at a later stage for processing the data, the raw data can similarly be processed using these algorithms to arrive at a final display of processed data.

In Figure 19, the body composition processing module 31 is shown. The module includes a 50kHz oscillator circuit 156 which, in conjunction with the constant current source circuit 158, through the application of suitable input electrodes 160, drives a constant 50kHz current through the patient's body. The voltage difference across the body is sensed via sensing electrodes 162, is converted to a DC voltage by a rectifier circuit 164, is low pass filtered to remove frequency components above 8Hz, and is presented to the main multiplexer 56 at the start of the common processing path 54. The signal passes through the common processing path 54 to emerge at the input to the PC-based processing path 166 of the body composition module. The signal is a fixed level signal which has no time information, and is converted to an impedance reading by a scaling routine 168 using data stored in the diagnostic unit during manufacture. The signal is smoothed by smoothing circuitry 170 to remove noise, and the signal level is recorded. This level is used in conjunction with height, mass and gender data 172 of the patient to calculate at 174 the body water-to-fat and other ratios. These results are displayed at

176. As was the case with the previous modules, raw data is stored in the buffer 178 and is transferred to the common database 102 if and when required for later processing.

It is possible to send test results to other parties by email. Any recipient of such a test result requires either a diagnostic system of the type described above or a viewer utility enabling it to view the data. Essentially, the viewer utility includes all the PC-based software signal processing routines which are downstream of the common signal processing path, with the processed data being retrieved off-line in all cases from the common database 102.

As the data in respect of a particular patient is stored indefinitely, comparisons can be made with updated data so as to enable trends in the results to be readily detected, thereby enabling chronic illnesses and treatment regimes to be monitored. The patient's vital functions can be monitored during clinical drug trials both before, during and after the trials, thereby enabling the trial results to be determined more rapidly, repeatedly and without any operator bias.

As the data is stored in a raw form in which all the signal information is preserved, historical raw data can be processed using updated processing techniques and algorithms, thereby ensuring consistency in respect of the process data. Either raw or processed data can be transmitted electronically to, or written on a portable storage medium to be sent to a remote specialist to whom the patient is being referred. If both the general practitioner and the specialist are online, the data can be reviewed in real time, and remote diagnosis can be performed without involving any delays arising from the transfer of the patient.

A further significant advantage arises in medico-legal applications, where historical raw data can be processed in a reliable and consistent fashion.

CLAIMS

1. A medical diagnostic apparatus comprising testing means for performing diagnostic tests on a patient, pre-processing means for deriving raw test data from the testing means, processing means for processing the raw test data into a user-discernible format, compression means for compressing the raw test data, and storage means for storing the compressed raw test data for subsequent retrieval and processing.

2. A medical diagnostic apparatus according to claim 1 which includes display means for displaying the processed data in the user-discernible format, and selection means for selecting a raw data storage option on the basis of the displayed processed data.

3. A medical diagnostic apparatus according to either one of the preceding claims 1 or 2 in which the testing means includes means for performing at least two tests chosen from a group comprising tests based on bio-electrical activity, tests based on blood pressure, tests based on lung function, and tests based on body composition.

4. A medical diagnostic apparatus according to claim 3 in which the pre-processing means includes a primary filtering means for removing out-of-band noise in respect of bandwidths which do not have a signal component of interest.

5. A medical diagnostic apparatus according to either one of claims 3 or 4 in which the testing means for performing tests based on bio-electrical activity includes an ECG testing module, the testing means for performing tests based on blood pressure includes a non-invasive blood pressure testing module, the testing means for

performing tests based on lung function includes a spirometer module, and the testing means for performing tests based on body composition includes a body composition testing module.

6. A medical diagnostic apparatus according to claim 5 in which the modules form part of a diagnostic unit which is arranged to transfer the raw data to a computer means for subsequent processing and storage.

7. A medical diagnostic apparatus according to claim 6 in which the processing means includes in-band filtering means for removing noise from a composite of noise and signal within a bandwidth of interest.

8. A medical diagnostic apparatus according to claim 7 in which the in-band filtering means is software-based, and is arranged to run on the computer means.

9. A medical diagnostic apparatus according to claim 2 which includes buffer means for temporarily storing the raw data prior to selecting the raw data storage option for compressing and storing the raw test data for subsequent retrieval and processing thereof.

10. A medical diagnostic apparatus according to any one of the preceding claims in which the database is linked to or forms part of a clinical patient record database, and is arranged to receive raw test data in respect of all of the tests and to include historical raw test data in respect of a plurality of patients.

11. A medical diagnostic apparatus according to claim 10 in which historical raw test data is arranged to be processed with current raw

test data using the same processing algorithms to achieve consistency for the purposes of trend analysis in respect of individual patients or for the purposes of comparing patients within a population group.

12. A method of acquiring medical data on a patient including the steps of deriving raw test data in electronic format from diagnostic tests which have been performed on the patient, processing the raw test data into a user-discernible format, compressing the raw test data, and storing the compressed raw data for subsequent retrieval and processing.

13. A method according to claim 12 which includes the step of displaying the processed data in the user-discernible format, and selecting a raw data storage option on the basis of the displayed processed data.

14. A method according to either one of the preceding claims 12 or 13 in which the raw test data is processed in accordance with one or more software-based algorithms to extract in-band noise from a composite of noise and signal within the band(s) of interest.

15. A method according to any one of the preceding claims 12 to 14 which includes the step of pre-processing the raw test data by removing out-of-band noise in respect of bandwidths which do not have a signal component of interest.

16. A method according to any one of the preceding claims 12 to 15 including the steps of obtaining raw analogue data from pressure variation tests, converting the analogue data to digital form, compressing the raw digital data and storing the compressed digital

data in a common database for subsequent retrieval and processing thereof.

17. A method according to claim 16 in which the pressure variation tests include non-invasive blood pressure tests and lung function or spirometry tests.

18. A method according to any one of the preceding claims 12 to 17 including the steps of obtaining raw analogue data from bio-electrical tests, converting the analogue data to digital form, compressing the raw digital data and storing the compressed digital data in a common database for subsequent retrieval and processing thereof.

19. A method according to any one of the preceding claims 12 to 18 including the steps of obtaining raw analogue data from body composition tests, converting the analogue data to digital form, compressing the raw digital data and storing the compressed digital data in a common database for subsequent retrieval and processing thereof.

20. A method according to any one of the preceding claims 12 to 19 which includes the subsequent steps of retrieving and decompressing the stored raw test data, processing data into a user-discernible format, in accordance with a software-based processing algorithm which is different to the software-based algorithm used originally to process the raw test data at the time of capture.

21. A method according to any one of the preceding claims 16 to 20 which includes the steps of storing in the common database clinical patient records, compiling a history of raw test data in respect of each patient, retrieving the raw test data and processing it in

accordance with at least one common algorithm for subsequent trend interpretation.

Fig 1

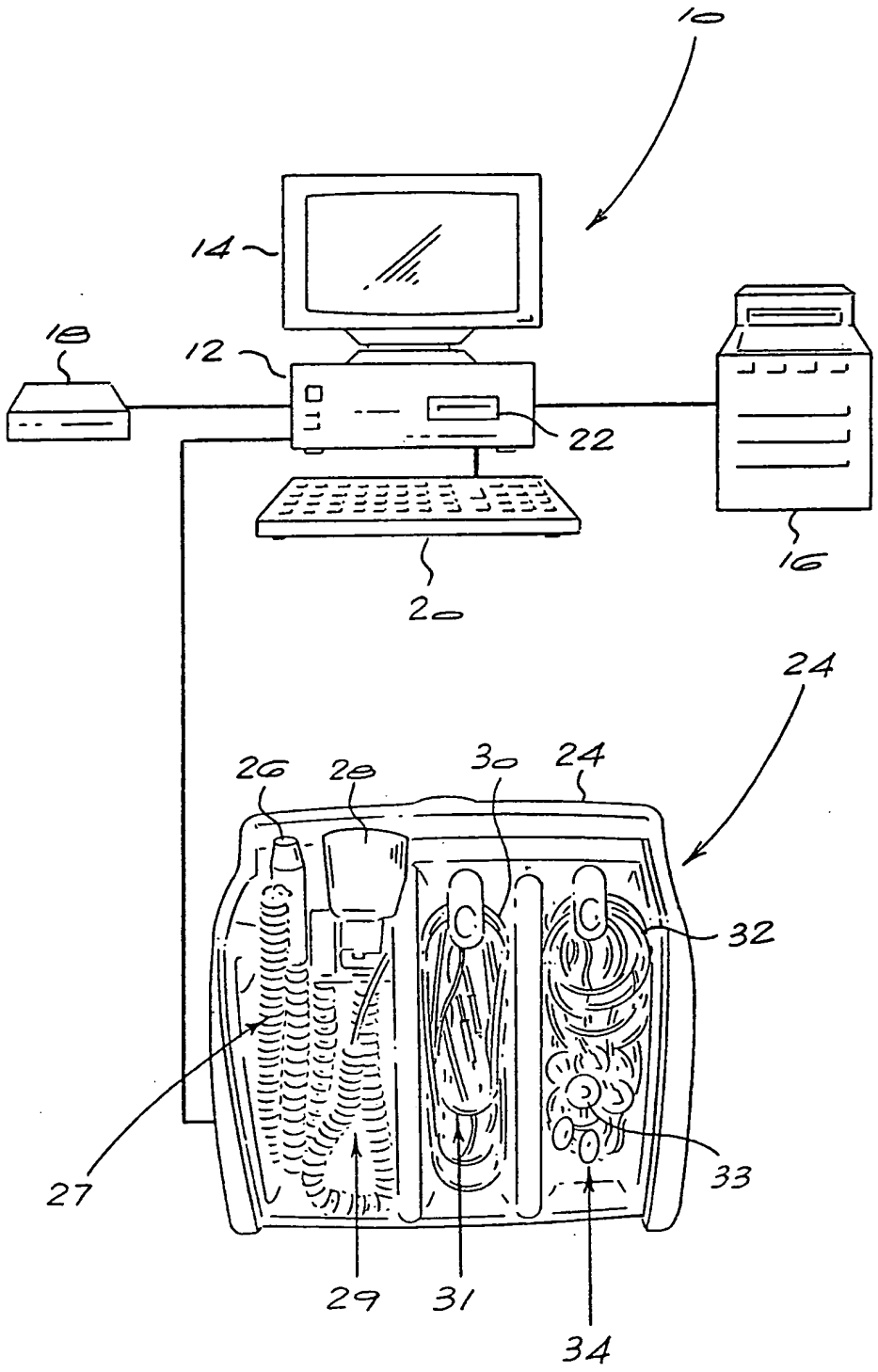


FIG 2

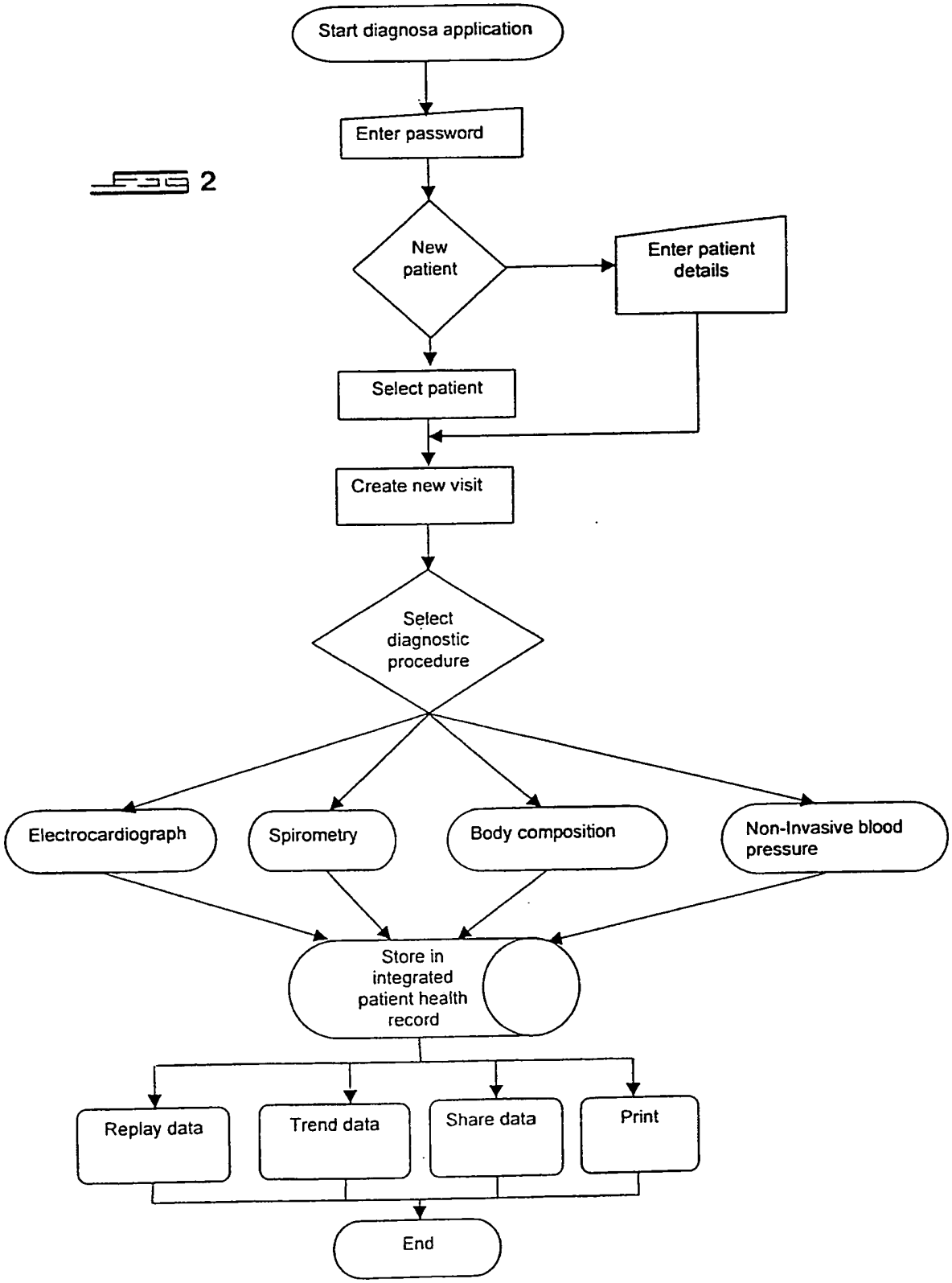

Start diagnosa application
Enter password
New patient
Enter patient details
Select patient
Create new visit
Select diagnostic procedure
Electrocardiograph
Spirometry
Body composition
Non-Invasive blood pressure
Store in integrated patient health record
Replay data
Trend data
Share data
Print
End

Fig 3

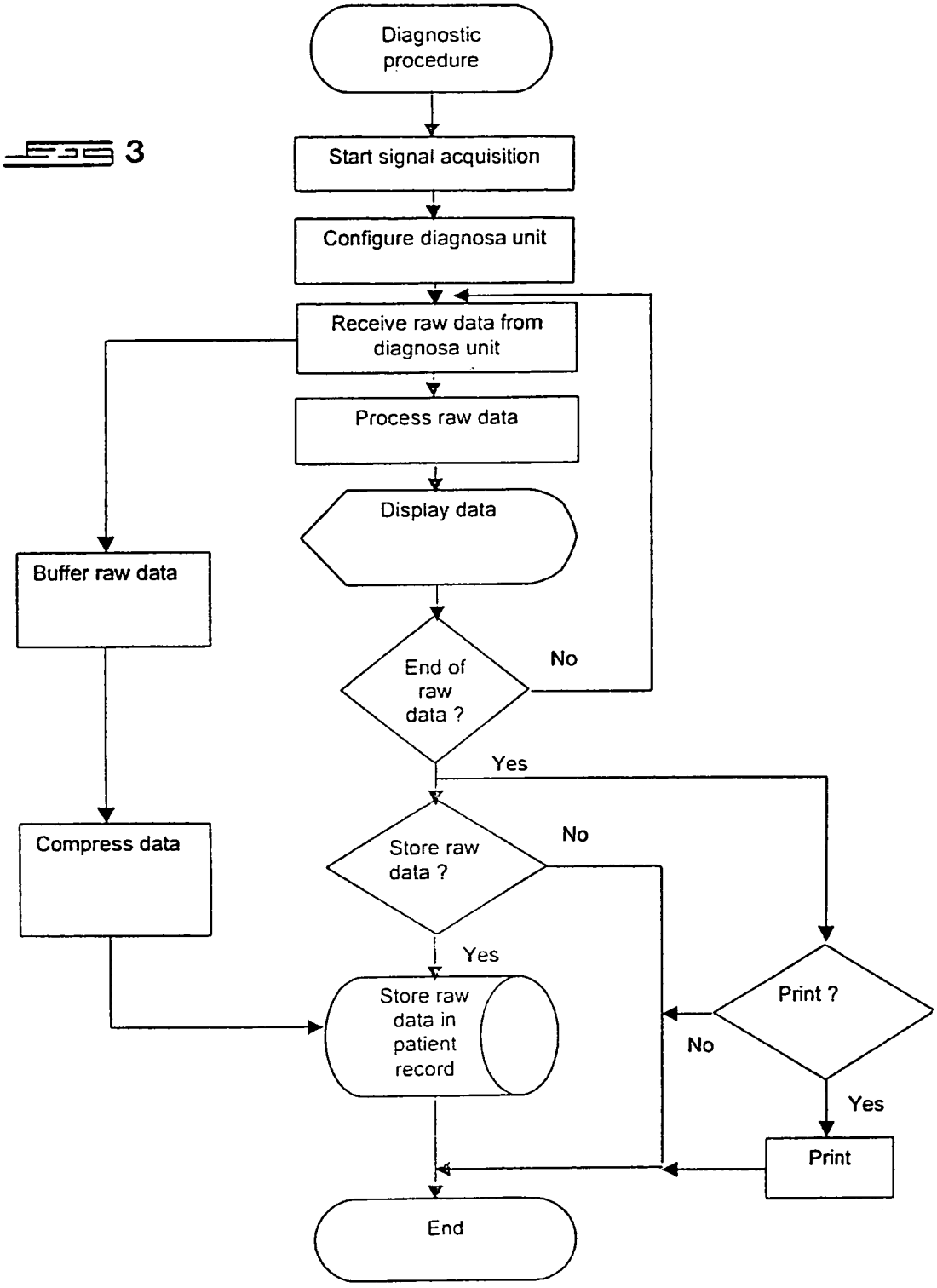

Diagnostic procedure
Start signal acquisition
Configure diagnosa unit
Receive raw data from diagnosa unit
Process raw data
Display data
Buffer raw data
End of raw data ?
No
Yes
Compress data
Store raw data ?
No
Yes
Store raw data in patient record
Print ?
No
Yes
Print
End

Fig 4

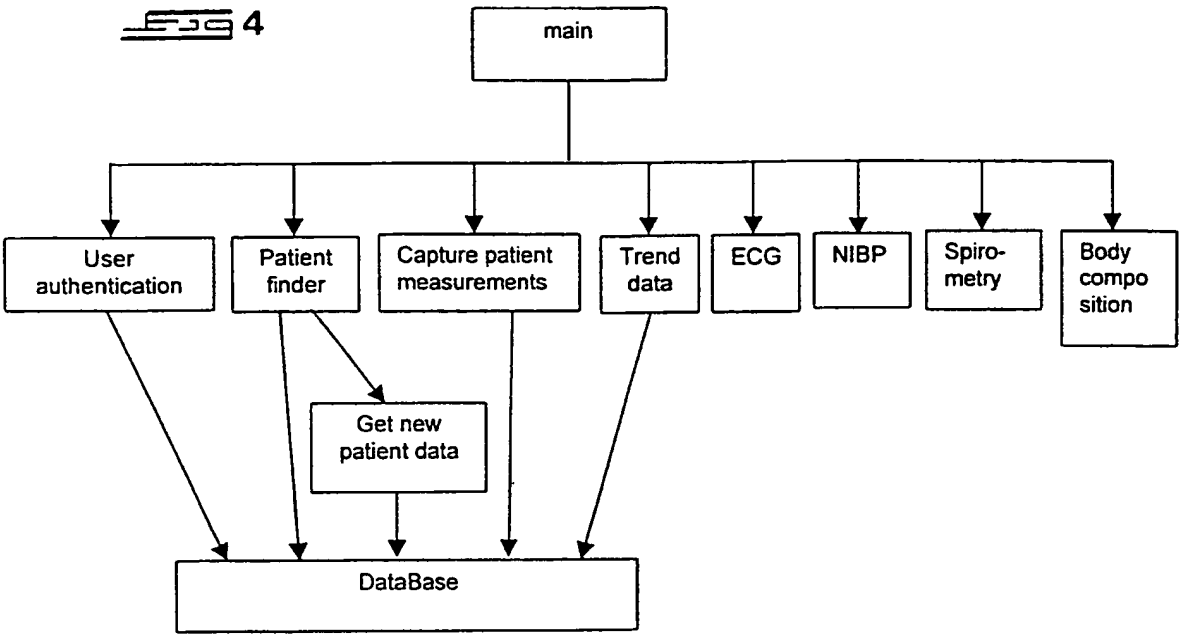

main
User authentication
Patient finder
Capture patient measurements
Trend data
ECG
NIBP
Spiro-metry
Body compo sition
Get new patient data
DataBase

Fig 5

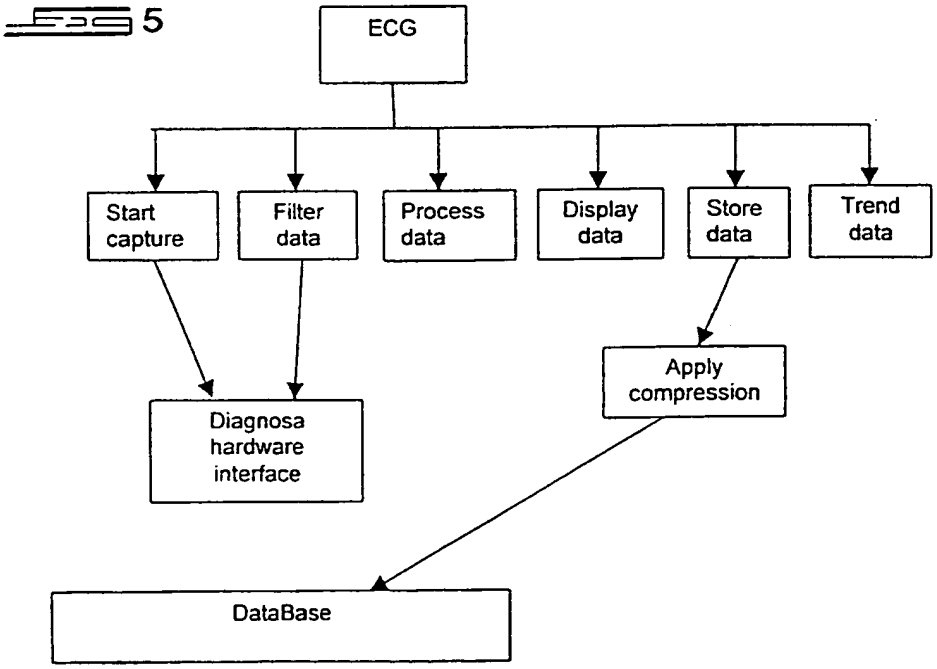

ECG
Start capture
Filter data
Process data
Display data
Store data
Trend data
Apply compression
Diagnosa hardware interface
DataBase

Fig 6

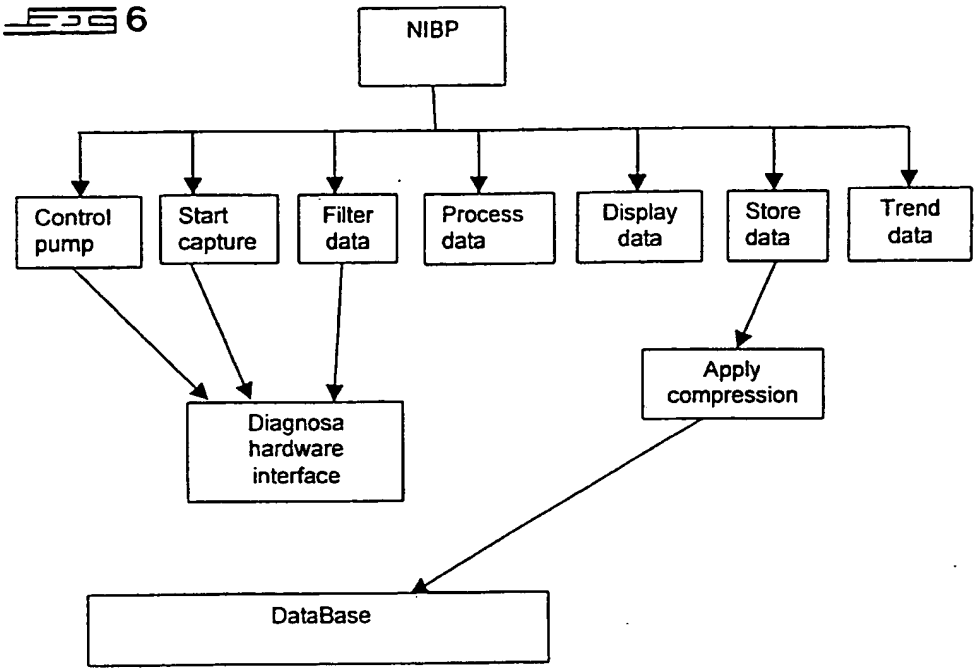

NIBP
Control pump
Start capture
Filter data
Process data
Display data
Store data
Trend data
Apply compression
Diagnosa hardware interface
DataBase

Fig 7

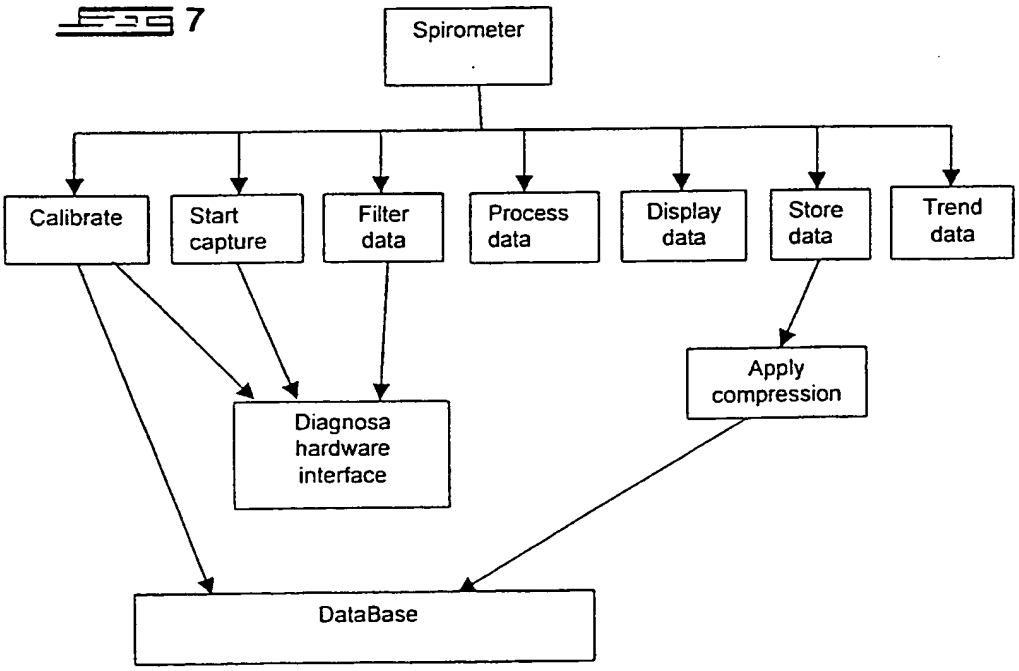

Spirometer
Calibrate
Start capture
Filter data
Process data
Display data
Store data
Trend data
Apply compression
Diagnosa hardware interface
DataBase

Fig 8

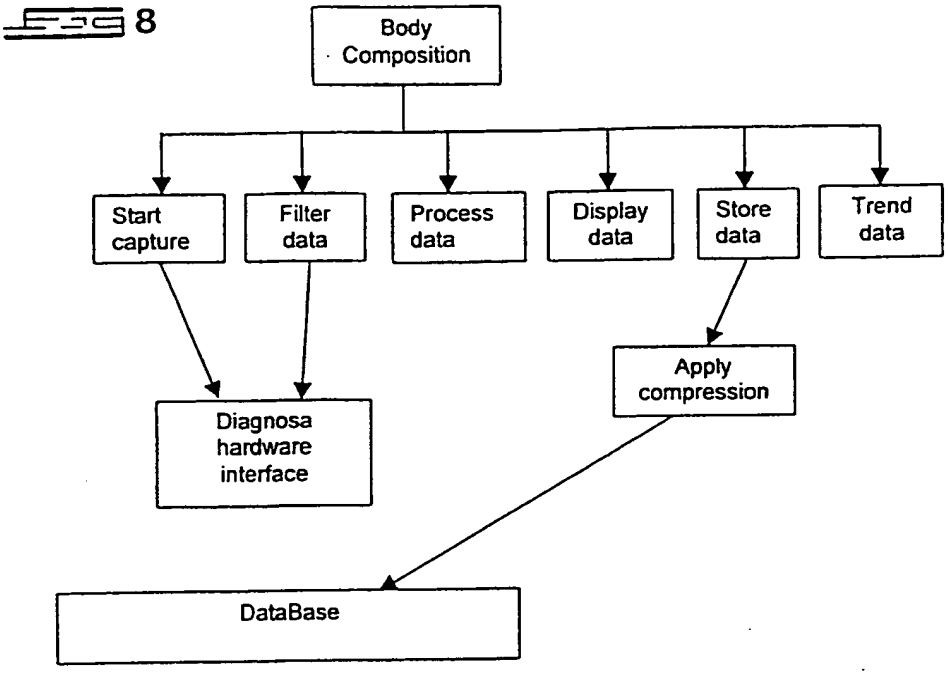
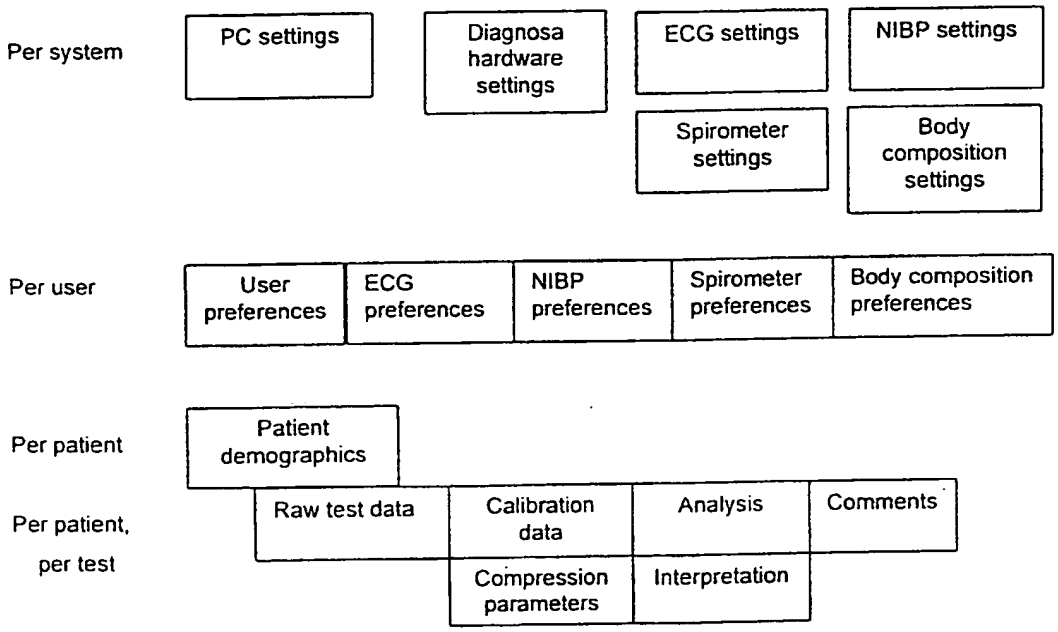

Body Composition
Start capture
Filter data
Process data
Display data
Store data
Trend data
Diagnosa hardware interface
Apply compression
DataBase

Fig 9


Per system
PC settings
Diagnosa hardware settings
ECG settings
NIBP settings
Spirometer settings
Body composition settings
Per user
User preferences
ECG preferences
NIBP preferences
Spirometer preferences
Body composition preferences
Per patient
Patient demographics
Per patient, per test
Raw test data
Calibration data
Analysis
Comments
Compression parameters
Interpretation

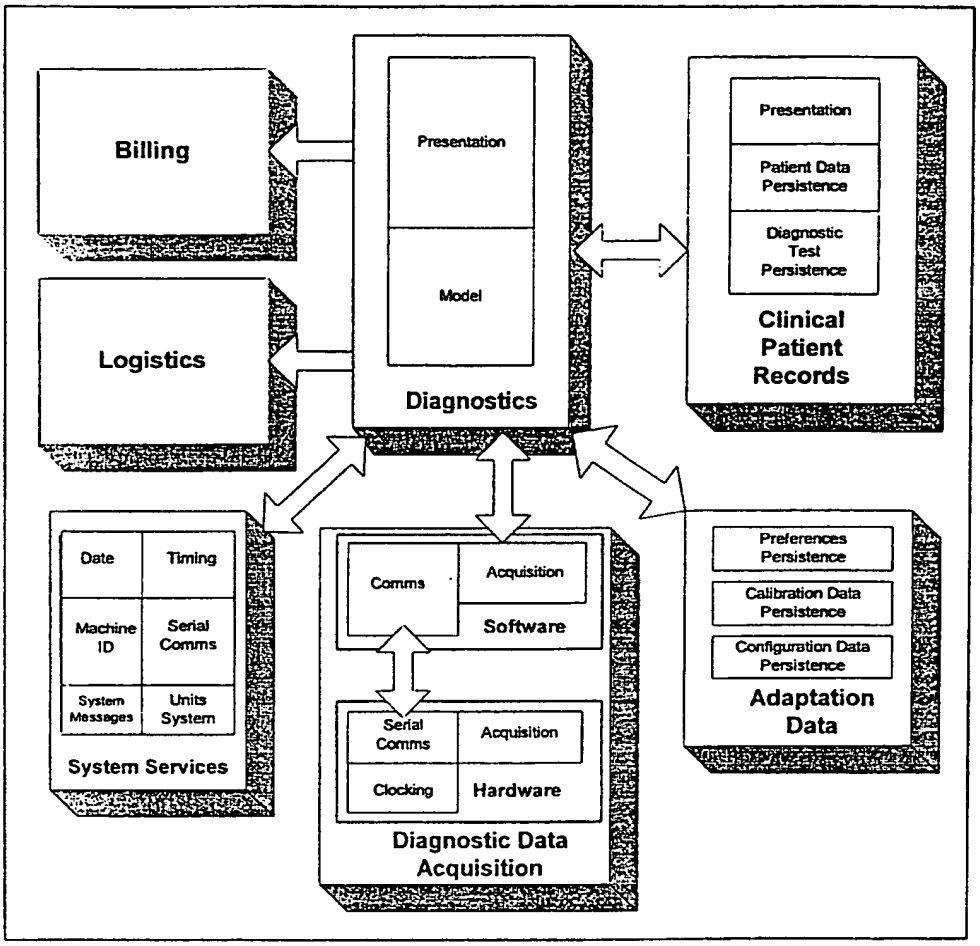

Billing
Logistics
Presentation
Model
Diagnostics
Presentation
Patient Data Persistence
Diagnostic Test Persistence
Clinical Patient Records
Date
Timing
Machine ID
Serial Comms
System Messages
Units System
System Services
Comms
Acquisition
Software
Serial Comms
Acquisition
Clocking
Hardware
Diagnostic Data Acquisition
Preferences Persistence
Calibration Data Persistence
Configuration Data Persistence
Adaptation Data

Fig 10

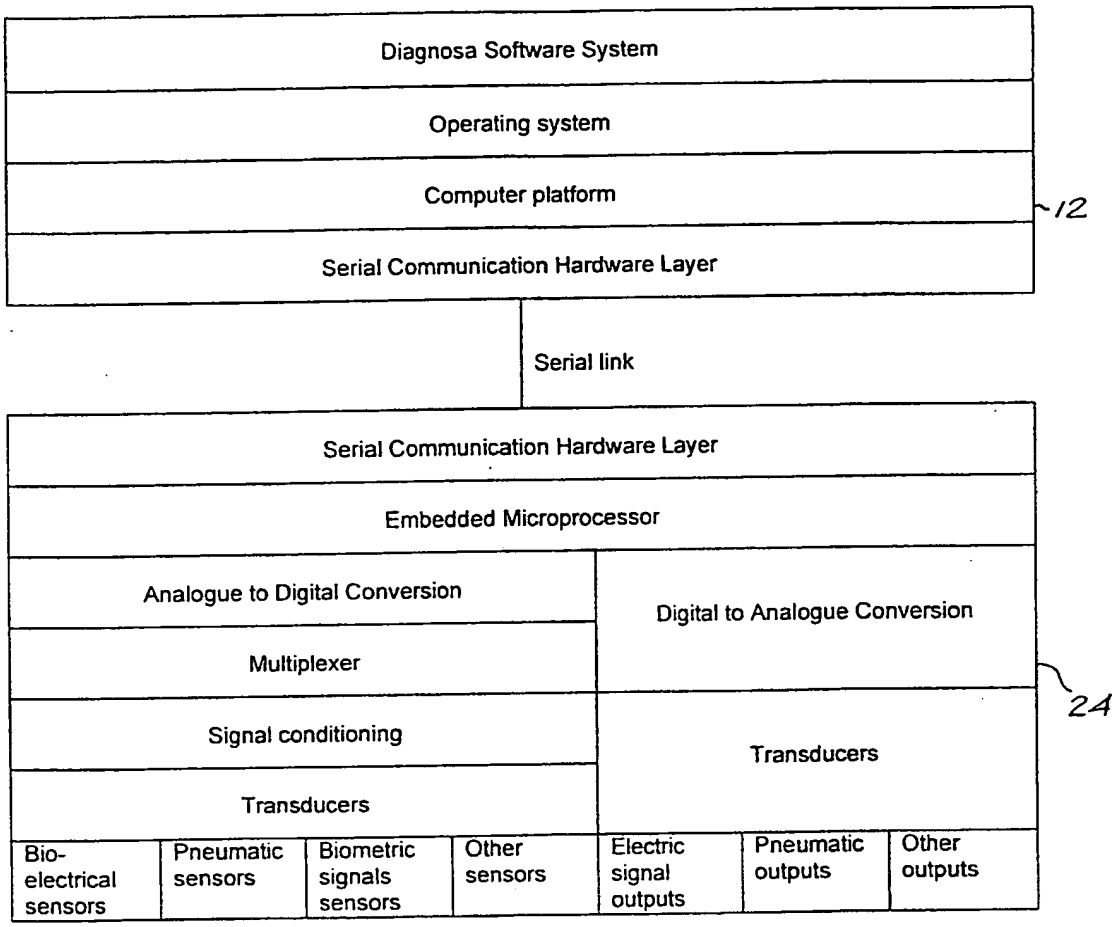
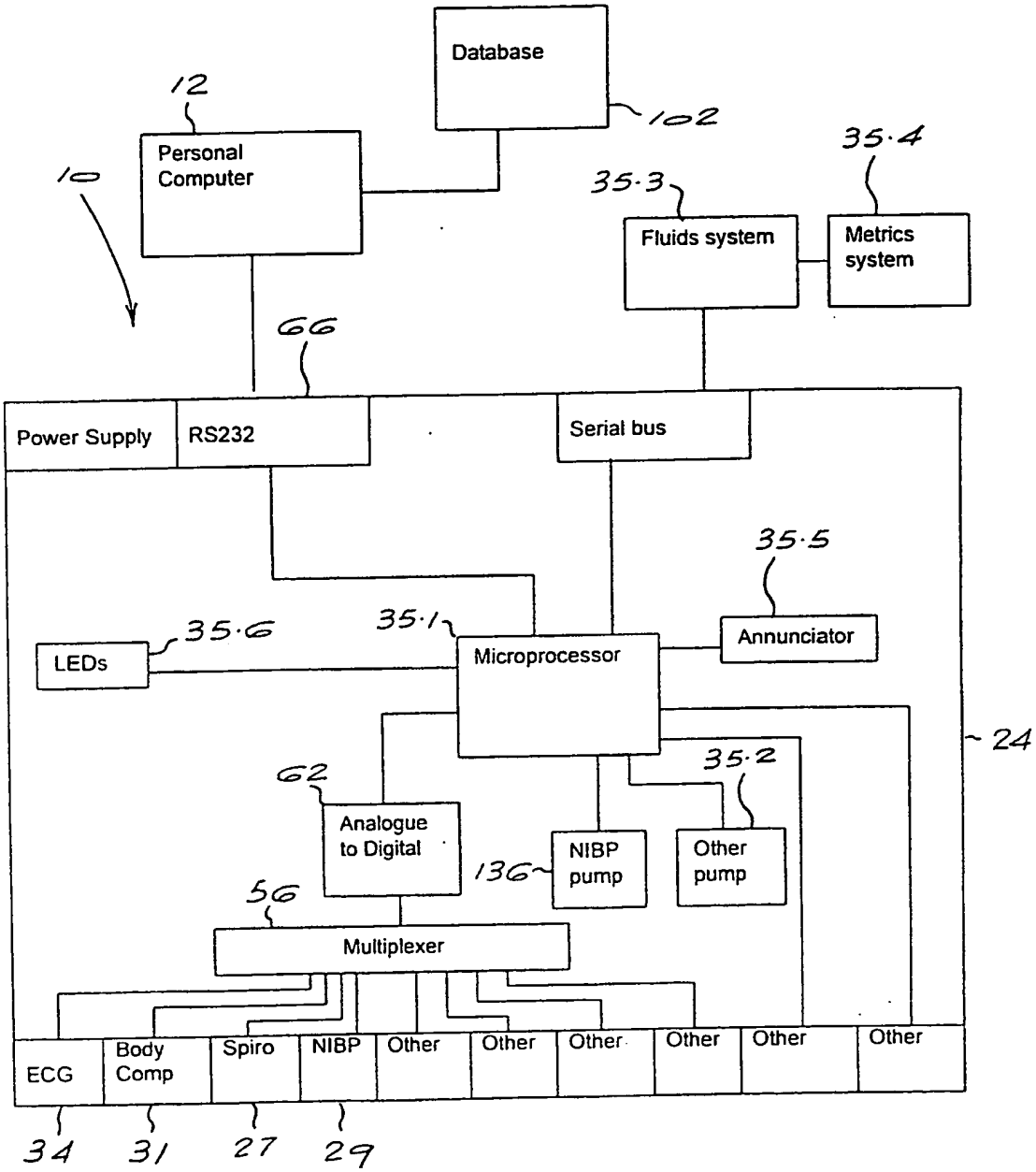

Diagnosa Software System
Operating system
Computer platform
Serial Communication Hardware Layer
12
Serial link
Serial Communication Hardware Layer
Embedded Microprocessor
Analogue to Digital Conversion
Multiplexer
Signal conditioning
Transducers
Digital to Analogue Conversion
Transducers
24
Bio-electrical sensors
Pneumatic sensors
Biometric signals sensors
Other sensors
Electric signal outputs
Pneumatic outputs
Other outputs

Fig 11

Fig 12


Database
102
12
Personal Computer
10
35.4
35.3
Fluids system
Metrics system
66
Power Supply
RS232
Serial bus
35.5
35.6
35.1
LEDs
Microprocessor
Annunciator
24
62
35.2
Analogue to Digital
NIBP pump
136
Other pump
56
Multiplexer
ECG
Body Comp
Spiro
NIBP
Other
Other
Other
Other
Other
Other
34
31
27
29

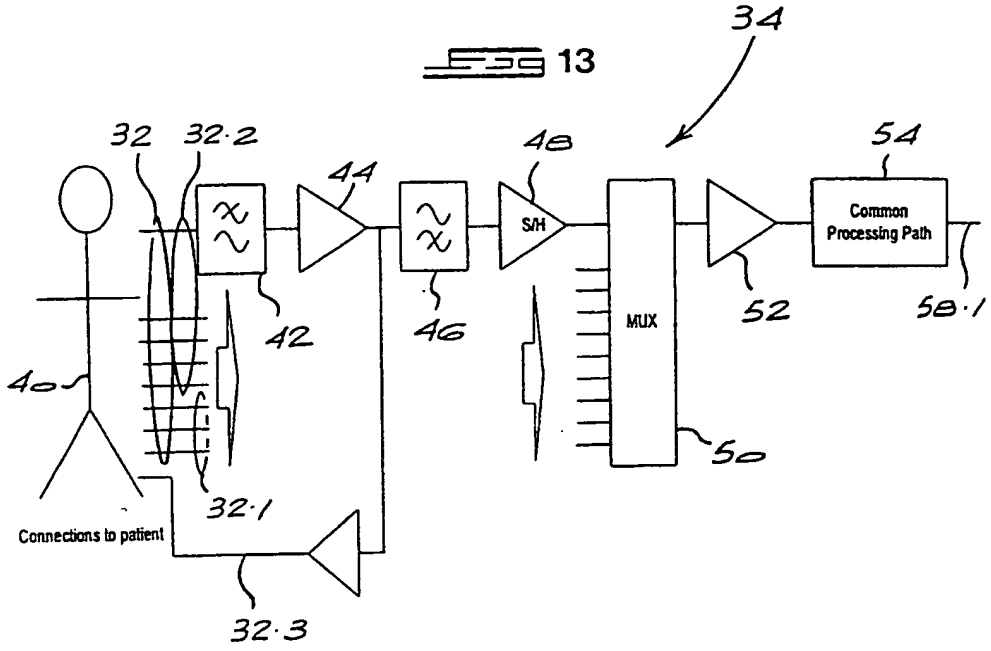

34
32
32.2
44
48
54
Common Processing Path
S/H
MUX
52
58.1
42
46
40
50
32.1
Connections to patient
32.3

FIG 13

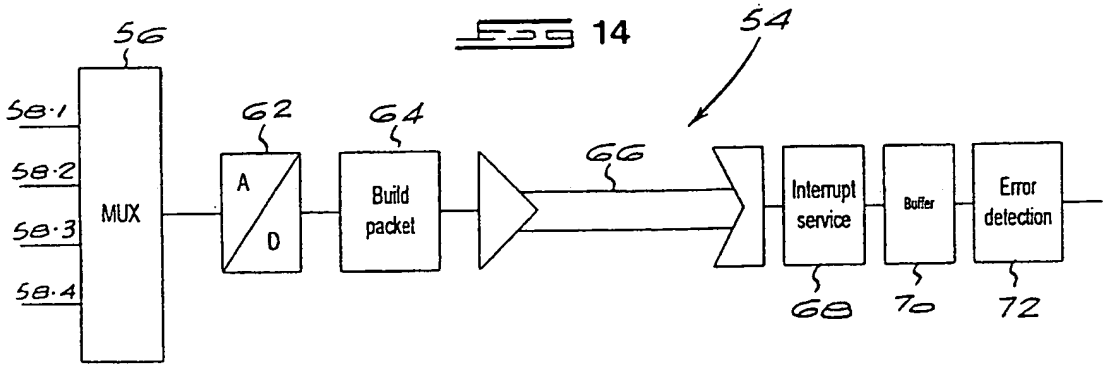

56
54
58.1
58.2
58.3
58.4
MUX
62
64
66
A
D
Build packet
Interrupt service
Buffer
Error detection
68
70
72

FIG 14

Fig 15

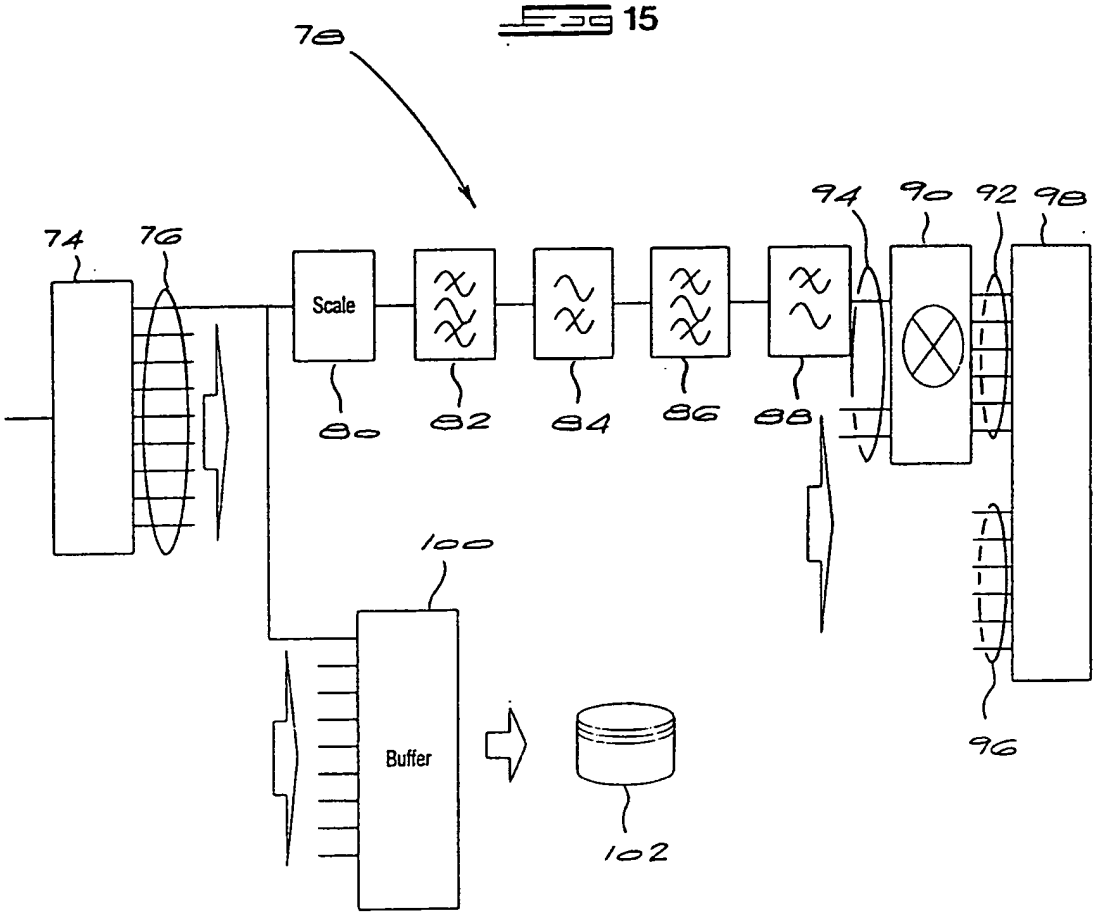
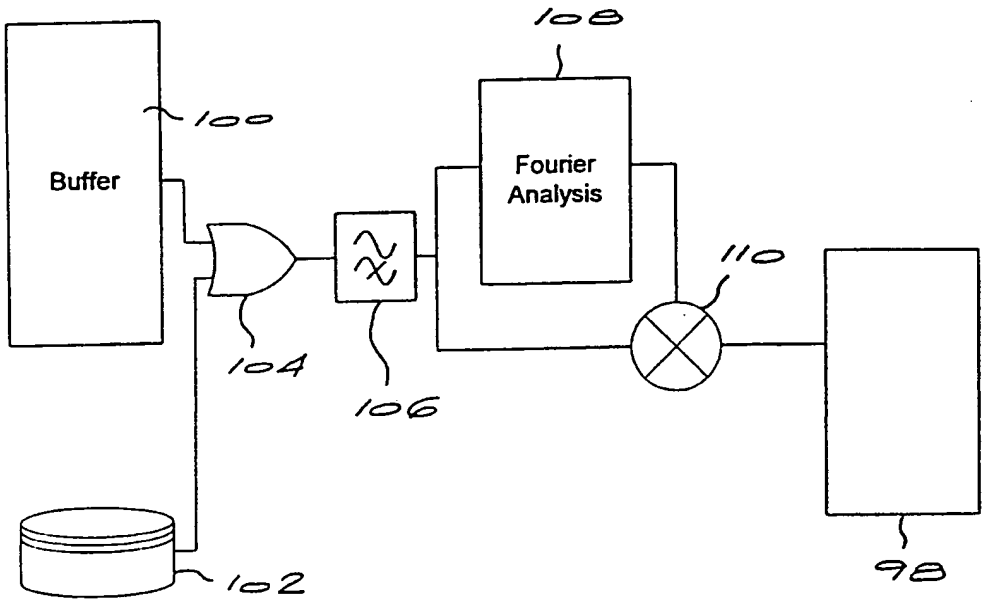


Fig 16



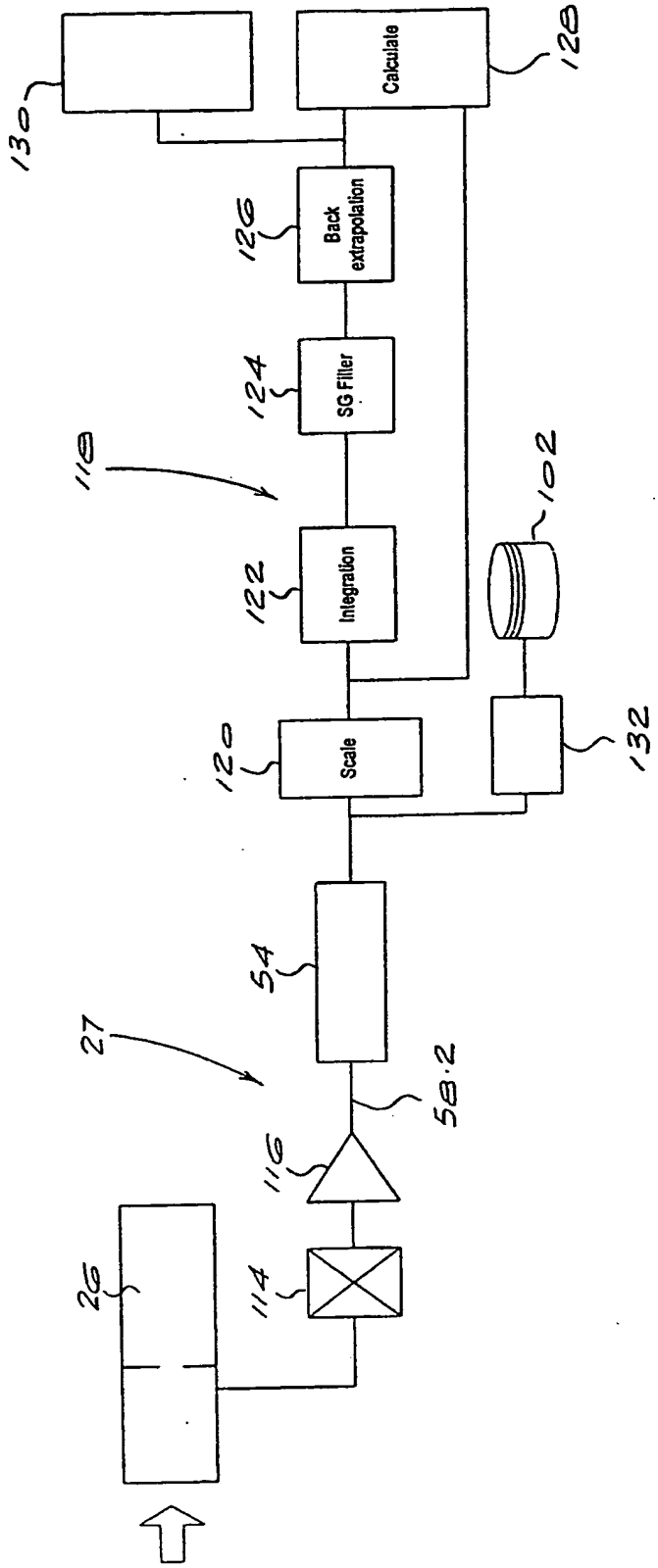

Calculate
128
130
Back extrapolation
126
SG Filter
124
118
102
Integration
122
Scale
120
132
54
27
58.2
116
114
26

FIG 17

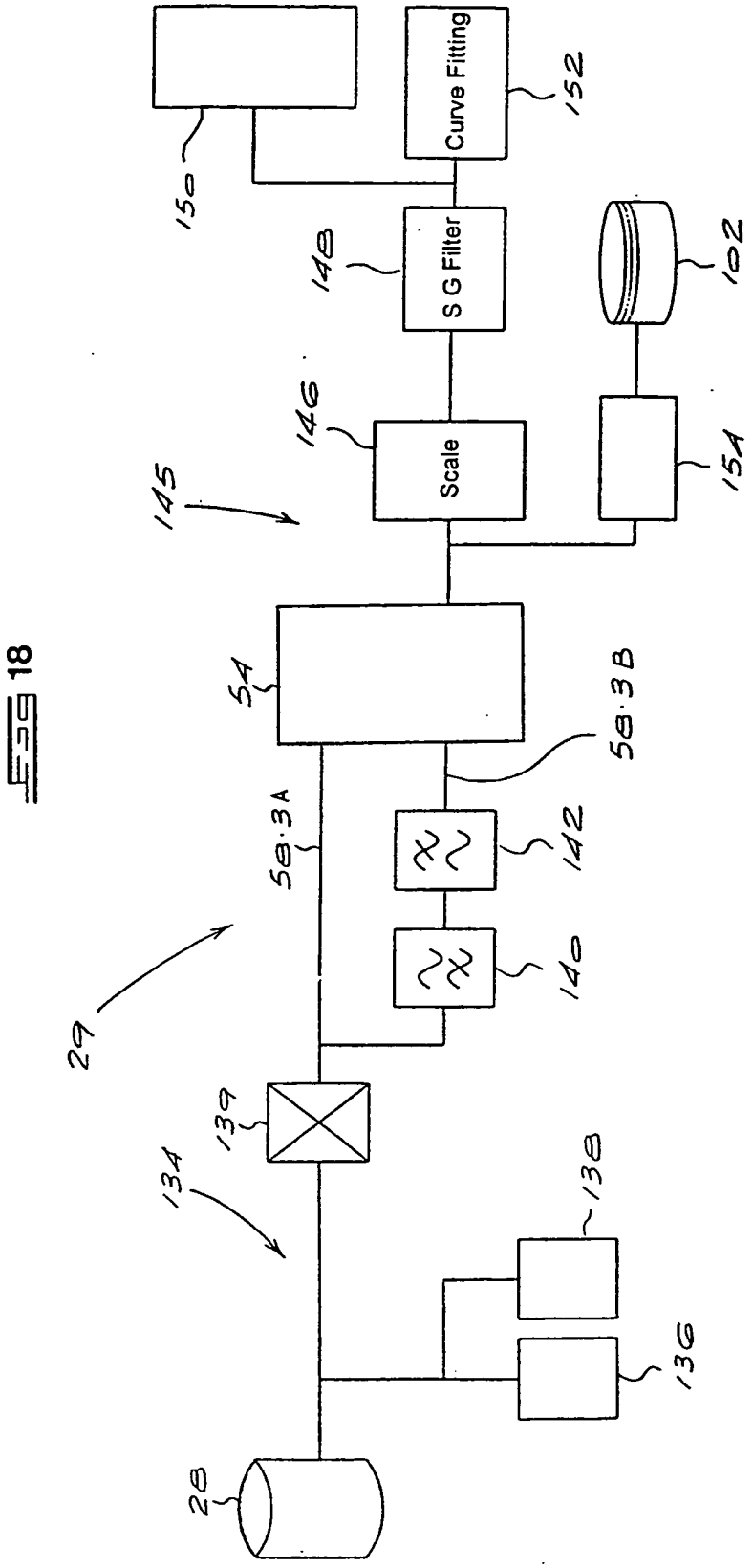

Curve Fitting
152
150
S G Filter
148
102
Scale
146
154
145
54
58-3B
58-3A
142
140
29
139
134
138
136
28

FIG 18

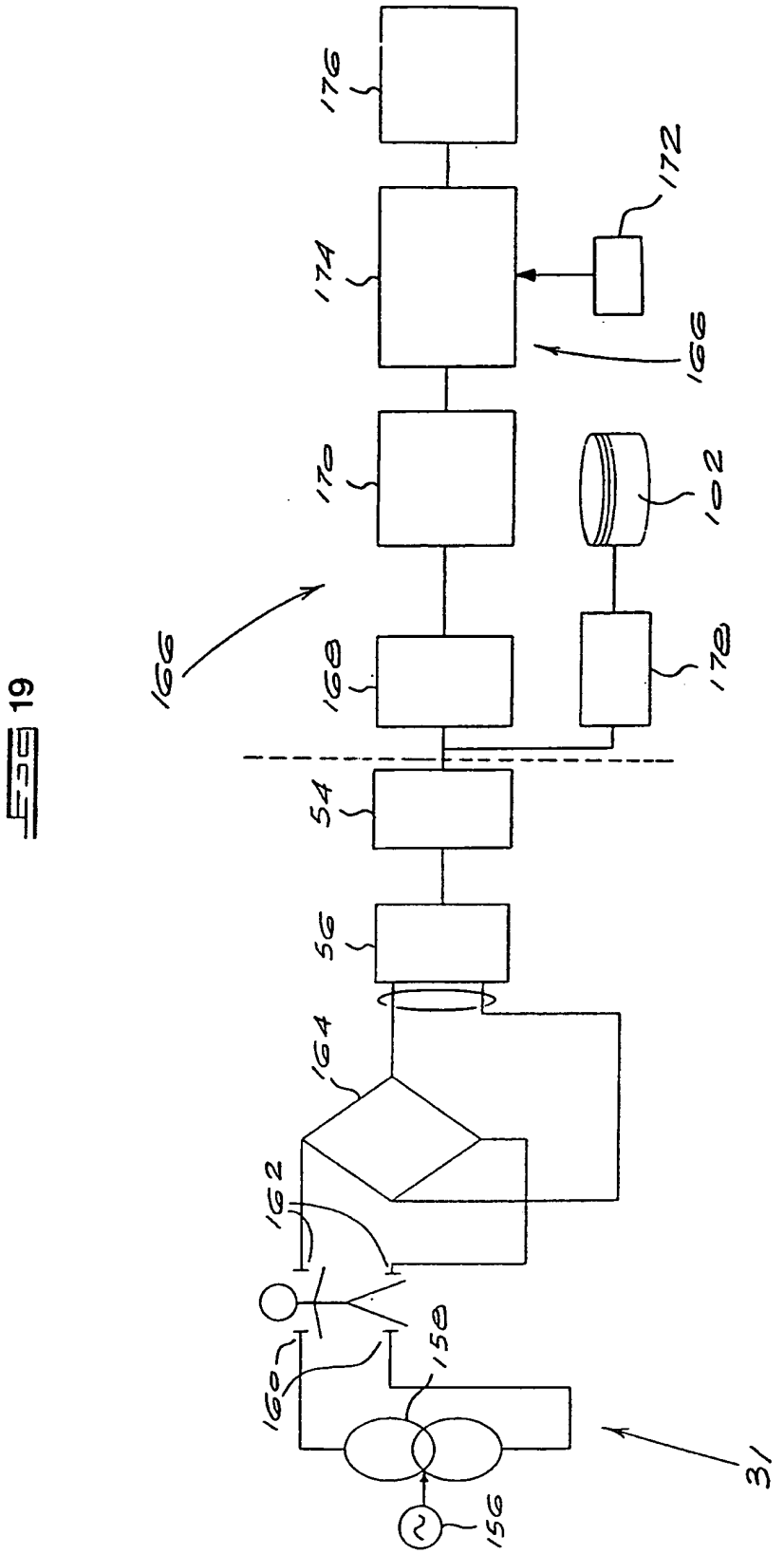


Fig 19